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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SPIEGLER, ALEXANDER H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1637 | |

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,509

Applicant(s)

BALTIMORE ET AL.

Examiner

Alexander H. Spiegler

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

1. This action is in response to Applicants' response filed on September 17, 2003. Currently, claims 1-10 are pending and are rejected herein. Applicant has cancelled Claim 11. This action is made NON-FINAL.

Election/Restrictions

2. Applicant's election of Group I (Claims 1-10) in Applicants' response of September 17, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

CRF/Sequence Notes

4. The Sequence Listing filed in this application complies with the requirements of 37 CFR 1.821-1.825 and has been entered.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. (See page 8, line 9) Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 9 over “said expression vector” because this recitation lacks antecedent basis, as Claim 1 does not recite “expression vector”.

B) Claim 10 is indefinite because it is not clear as to whether dividing said plurality of candidate agents occurs before, simultaneously or after the activity is determined. For example, are the method steps of Claim 1(i)-(iii) carried out, and then candidate agents are divided, or does the dividing occur simultaneously while a plurality of agents are being introduced to some cells or does the dividing occur before the method steps of Claim 1(i)-(iii).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-4 and 6-10 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Glimcher et al. (USPN 5,958,671).

Regarding Claims 1 and 10, Glimcher teaches a method for screening for an agent, which modulates transcription factor activity, comprising:

(i) providing a cell comprising a transcription factor of interest and a vector comprising a binding site for said transcription factor of interest operatively linked to a reporter gene;

(ii) introducing a plurality of candidate agents to said cell; and

(iii) determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agents indicates the presence of an agent which modulates transcription factor activity. (See cols. 3-4, 6-19, 31-34 and Examples 1-7)

Regarding Claim 2, Glimcher teaches the agent can be cDNA clones from an expression library (col. 8, line 62 to col. 9, line 31 and col. 14, lines 25-44, for example).

Regarding Claim 3, Glimcher teaches introducing into said cell a control plasmid comprising a constitutively expressed gene to monitor transfection efficiency (see col. 11).

Regarding Claim 4, Glimcher teaches the reporter gene is a luciferase gene (col. 32, lines 22-28).

Regarding Claims 6-7, Glimcher teaches the activity is inhibited or stimulated (see cols. 3-4 and 8-19).

Regarding Claims 8-9, Glimcher teaches the cell can be a mammalian cell and the expression vector is a mammalian expression vector (see cols. 9-11).

10. Claims 1 and 3-10 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Kushner et al. (Pub No. US2002/0098477).

Regarding Claims 1 and 10, Kushner teaches method for screening for an agent, which modulates transcription factor activity, comprising:

- (i) providing a cell comprising a transcription factor of interest and a vector comprising a binding site for said transcription factor of interest operatively linked to a reporter gene;
- (ii) introducing a plurality of candidate agents to said cell; and
- (iii) determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agents indicates the presence of an agent which modulates transcription factor activity. (See pages 1-5 and 7 generally, and specifically paragraphs [0009]-[0018], [0040]-[0045], [0072-0084], and the Examples on pages 8-12).

Regarding Claim 3, Kushner teaches introducing into said cell a control plasmid comprising a constitutively expressed gene to monitor transfection efficiency (see pages 8-9, paragraph [0100], for example).

Regarding Claims 4-5, Kushner teaches the reporter gene can be a luciferase gene or a green fluorescent protein (page 2, paragraph [0015]).

Regarding Claims 6-7, Kushner teaches the activity is inhibited or stimulated (see pages 4-5).

Regarding Claims 8-9, Kushner teaches the cell can be a mammalian cell and the expression vector is a mammalian expression vector (see pages 3-5).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Glimcher et al. (USPN 5,958,671), as applied to claims 1-4 and 6-10 above, and further in view of Kushner et al. (Pub No. US2002/0098477).

The teachings Glimcher et al. are presented above. Specifically, Glimcher teaches method for screening for an agent, which modulates transcription factor activity, comprising:

- (i) providing a cell comprising a transcription factor of interest and a vector comprising a binding site for said transcription factor of interest operatively linked to a reporter gene;
- (ii) introducing a plurality of candidate agents to said cell; and

(iii) determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agents indicates the presence of an agent which modulates transcription factor activity. (See cols. 3-4, 6-19, 31-34 and Examples 1-7)

While Glimcher teaches “a variety of reporter genes are known in the art and are suitable for use in the screening assays of the invention”, Glimcher does not teach the use of a fluorescent protein. (See col. 32, lines 22-23)

However, Kushner teaches methods of screening an agent, which modulates transcription factor activity comprising, providing a cell comprising a transcription factor of interest and a vector comprising a binding site for said transcription factor of interest operatively linked to a reporter gene, wherein the reporter gene is a green fluorescent protein (See pages 1-5 and 7 generally, and specifically paragraphs [0009]-[0018], [0040]-[0045], [0072-0084], and the Examples on pages 8-12). Kushner teaches using green fluorescent protein is advantageous, since the green fluorescent protein provides an “easily assayable product” (see page 7, paragraph [0080]).

Accordingly, in view of the teachings of Kushner, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Glimcher so as to have used the green fluorescent protein as a reporter gene. One of ordinary skill in the art would have been motivated to modify the teachings of Glimcher to have used a green fluorescent protein as a reporter gene, in order to achieve the benefits stated by Kushner of providing an “easily assayable product” for detection purposes.

Conclusion

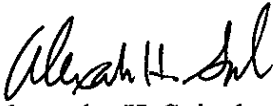
14. No claims are allowable.

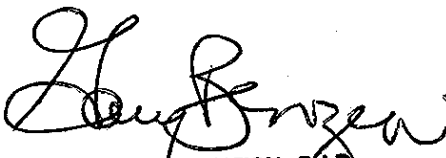
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806 or (571) 272-0788 after January 22, 2004. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199 or at (571) 272-0747 after January 13, 2004. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119 or at (571) 272-0782 after January 22, 2004. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Alexander H. Spiegler
January 2, 2004


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